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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,448	01/04/2001	Susan I. Shelso	06530.0275	3427

22852 7590 11/22/2005

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EXAMINER

PRONE, CHRISTOPHER D

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/753,448	<b>Applicant(s)</b> SHELSON, SUSAN I.	
	<b>Examiner</b> Christopher D. Prone	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-21, 23-34, 36-41, 43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-21, 23-34, 36-41, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/19/05 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 recites that the holding sleeve is positioned about the tubular member and is "configured to retain the stent around the holding sleeve." It is unclear how the holding sleeve will retain the stent about itself.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7-13, 15, 16, 29, 30, 32-34 and 44 rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft (USPN 5,702,418) in view of St. Germain et al (USPN 5534,007).

With reference to Figure 1, Ravenscroft discloses a delivery system (10) comprising a catheter (11) having self-expanding stent (20) disposed on distal end near a loading funnel (13). Figure 1 shows that loading funnel (13) is used to compress stent (20) on the distal end of catheter (11) within a slidable outer member (24) during delivery into the patient's body. The catheter (11) further comprises a guidewire (31) and a tubular member (17) comprising at least three radiopaque marker bands (37) shown in Figure 5 as 4 dark rings that indicate the leading, middle, and trailing ends of stent (20). Ravenscroft further discloses that the distal tip (13) may be made of radiopaque material or comprise a radiopaque marker band, which corresponds to the distal most tip of the stent (20). The catheter also has an outer member (24) that is slidable relative to the tubular member (5:15-22) is configured to retain the stent 20 in a radially compressed position. In one embodiment Ravenscroft discloses an inflatable balloon device (60) disposed on the catheter beneath the stent (7:10-13). The marker bands can be used to indicate a position corresponding to the re-constrain limit of a partially deployed stent (7:53-59). The catheter further comprises fluid ports (30) shown in figure 4, which are capable of conveying fluids to the inflatable device (60) between the tubular member (17) and outer member (24). Ravenscroft also discloses the

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method for implanting a self-expanding stent comprising the following steps; providing the stent/deployment system combination, delivering the system to the target region, partially deploying the stent, re-constraining the stent, and inflating the balloon device to assist the expansion of the stent (6:21-58 and 7:1-41). Ravenscroft discloses the delivery system for a self-expanding stent as claimed. Ravenscroft however fails to disclose a holding sleeve configured to retain the positioning of the stent, wherein the inflatable device is disposed solely between the holding sleeve and the distal end of the catheter.

St. Germain teaches an integrated balloon catheter delivery device comprising fluid port (130) for providing fluid to fill a balloon, guidewire (20), guidewire lumen (15), and a holding sleeve (60) in order to prevent the stent 35 from moving proximally when the distal sheath (40) is retracted. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the delivery system as disclosed by Ravenscroft by including a holding sleeve as taught by St. Germain in order to ensure proper positioning and that the entire stent is released from the outer member during deployment of the stent.

Claims 5, 6, 17-21, 23-28, 31, 36-41, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft as modified by St. Germain and further in view of Lenker et al (USPN 5,749,921).

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Ravenscroft, as discussed above, discloses the stent delivery device as claimed. Ravenscroft however fails to teach the loading the stent onto the delivery system through the delivery funnel.

Lenker teaches a the device and method of loading a stent 72 into a delivery catheter prior to deployment by attaching removable cartridge 102 comprising flared portion 100 thereby allowing the stent to be loaded in the operating room prior to deployment to avoid shipping and storing the prosthesis in a compressed configuration (7:1-25). After the stent 72 is loaded within sheath 106 it is detached from the delivery system and disposed at the end of a delivery catheter.

Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the delivery device disclosed by Ravenscroft and modified by Fischell in order to incorporate the method of loading the stent as taught by Lenker in order avoid storing the stent in a compressed configuration thereby promoting resilient expansion of the stent to its full diameter when it is released.

### ***Response to Arguments***

Applicant's arguments with respect to all the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher D Prone  
Examiner  
Art Unit 3738

  
CDP

  
CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
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